DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 13, 2015

Bard Access Systems, Inc.
M.s Amy McManus
Regulatory Affairs Specialist II
605 North 5600 West
Salt Lake City, UT 84116

Re: K142445
Trade/Device Name: Pinpoint™ GT Safety Introducer Needle
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II
Product Code: DYB
Dated: March 12, 2015
Received: March 13, 2015

Dear Ms. McManus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BARD
ACCESS SYSTEMS

Indications for Use

510(k) Number (if known): K142445

Device Name: Pinpoint™ GT Safety Introducer Needle

Indications for Use:

The Pinpoint™ GT Safety Introducer Needle is intended for patients requiring percutaneous access to place a guidewire for subsequent placement of catheters or other medical procedures requiring introducer needle access. The Pinpoint™ GT Safety Introducer Needle may be used in any appropriate patient population.

Prescription Use ✓ . (Part 21 CFR §801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

K142445

BARD
ACCESS SYSTEMS

510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name:	Bard Access Systems, Inc.
	Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Amy McManus Regulatory Affairs Specialist II
	Telephone Number:	(801) 522-5724
	Fax Number:	(801) 522-5425
	Date of Preparation:	April 10, 2015
Subject Device	Trade Name:	Pinpoint™ GT Safety Introducer Needle
	Common Name:	Safety Introducer Needle
	Classification Name:	Catheter Introducer
	Product Code/ Regulation:	DYB/21 CFR §870.1340
Predicate Device	Predicate Trade Name:	SecureLoc™ Safety Introducer Needle
	Classification Name:	Catheter Introducer
	Premarket Notification:	K050023
	Manufacturer:	Bard Access System, Inc.
Reference Device	Reference Device Trade Name:	Soma Access Systems ExactTrack™ I Procedure Kit
	Classification Name:	Ultrasonic Pulsed Echo Imaging System
	Premarket Notification:	K113680
	Manufacturer:	Soma Access Systems LLC
Device Description	Bard Access Systems, Inc.'s, Pinpoint™ GT Safety Introducer Needle is designed for percutaneous access to introduce a guidewire. The Pinpoint™ GT Safety Introducer Needle contains a magnet which emits a passive magnetic field that can be detected by Ultrasound Systems equipped with Pinpoint™ GT Technology. The Pinpoint™ GT Safety Introducer Needle, when used with the Pinpoint™ GT System creates a virtual image of the needle on the Ultrasound display, providing clinicians with a visual representation of the needle throughout the insertion process.	

Intended Use	The Pinpoint™ GT Safety Introducer Needle is designed for percutaneous vasculature access or procedures requiring the placement of a guidewire.
Indications For Use	The Pinpoint™ GT Safety Introducer Needle is intended for patients requiring percutaneous access to place a guidewire for subsequent placement of catheters or other medical procedures requiring introducer needle access. The Pinpoint™ GT Safety Introducer Needle may be used in any appropriate patient population.
Technological Characteristics	Technological characteristics of the subject Pinpoint™ GT Safety Introducer Needle are substantially equivalent with respect to basic design and function to those of the predicate, Bard Access Systems, Inc.'s SecureLoc™ Safety Introducer Needle. The differences are not critical to the intended use of the device and do not raise any new questions regarding safety or effectiveness.

Table1– Subject Device Attribute and Technology Comparison Table			
Device Attribute	**Subject:** **Pinpoint™ GT Safety Introducer Needle**	**Primary Predicate:** ***Introducer Needle SecureLoc™***	**Reference Device:** ***Magnet Tracking System (Needle Technology*** **ExactTrack™ I Procedure Kit (AKA AxoTrack™))**
Owner	**Bard Access Systems, Inc.**	**Bard Access Systems, Inc.**	**Soma Access Systems LLC.**
Needle Components	Needle tip: -Echogenic -A Bevel Open ended luer locking hub Bevel Indicator Incorporated active safety mechanism Passive Magnet	Needle tip: -Available as Echogenic and non-echogenic -Modified B Bevel Open ended luer locking hub Bevel Indicator Incorporated active safety mechanism	Needle tip: -Bevel type is not publically available Hub Bevel Indicator Does not contain a safety mechanism Passive Magnet
Needle Dimensions	• Length: 7 cm • Diameter: 21 gauge	• Length: 5.08 -8.89 cm • Diameter: 18, 19 and 21 gauge	• Length: Information not publically available • Diameter: 18 gauge
Needle-shield (Safety Mechanism) feature description	The Pinpoint™ GT Safety Introducer Needle includes an active safety guard mechanism. The safety guard is manually activated by the user sliding the	Needle includes an active safety guard mechanism. The safety guard is manually activated by the user. The user sliding the mechanism	Device does not contain a safety mechanism.

Table1– Subject Device Attribute and Technology Comparison Table			
Device Attribute	**Subject:** **Pinpoint™ GT Safety Introducer Needle**	**Primary Predicate:** ***Introducer Needle SecureLoc™***	**Reference Device:** ***Magnet Tracking System (Needle Technology*** **ExactTrack™ I Procedure Kit (AKA AxoTrack™))**
	mechanism down the needle cannula and over the needle tip. As the safety mechanism passes over the needle tip the safety locks into place, securing and covering the tip.	down the needle cannulation and over the needle tip; as the mechanism passes over the needle tip the safety locks into place, securing and covering the tip.	*The data was gathered from publicly available resources. See Attachment 4 for all resources used.*
Guidewire Compatibility	*21 Ga Needle* Same as Primary Predicate GW OD ≤ 0.018"	*21 Ga Needle* GW OD ≤ 0.018"	*18 Ga Needle* GW OD ≤ 0.035" (0.89 mm)

Performance Tests	Verification and validation tests have been performed in accordance with Design Controls as per 21 CFR §820.30. The following guidance documents and standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device: • *ISO 11070: 1998, Sterile, single use intravascular catheter introducer* • *ISO 594-1: 1986, Conical fittings with 6% luer taper for syringes, needles and certain other medical equipment – Part 1: General Requirements* • *ISO 594-2: 1998, Conical fittings with 6% luer taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings* • *ISO 9626: 2001, Stainless steel needle tubing for the manufacturer of medical devices* • *BSI BS EN ISO 23908: 2013, Sharps injury protection* • *ISO 7864: 1993, Sterile hypodermic needles for single use* • *Guidance Document; Medical Devices with Sharps Injury Prevention Features, August 9, 2005* • *Guidance on the Content of Premarket Notification [510(k)] Submissions for Hypodermic Single Lumen Needles, April 1993.* • *Guidance Document; Applying Human Factors and Usability Engineering to Optimize Medical Device Design, June 22, 2011* • *ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile* • *ISO 10993-7:2008, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals* • *ISO 11135:2007, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization* • *ISO 6009: 1992, Hypodermic Needles for Single Use- - Colour Coding for Identification* The subject device met all predetermined acceptance criteria derived from the above listed references and demonstrated substantially equivalent performance as compared to the cited predicate device. Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with ISO 14971:2012, *Medical Devices – Risk Management for Medical Devices.*

Performance Tests	**Performance Testing- Bench:** • Dimensional Analysis • Assembly Leak • Hub to Cannula Bond Strength • Needle Stiffness • ISO Luer Compliance • Guidewire Compatibility • Safety Mechanism Override • Visual Inspection • Corrosion • Usability and Simulated Use • Blood Flash • Echogenicity • Magnet Testing • Particulate testing (USP <788>) **Biocompatibility Testing:** • Cytotoxicity • Sensitization • Intracutaneous • Acute Systemic Toxicity • Pyrogenicity • Rabbit Blood Hemolysis • Unactivated partial Thromboplastin Time Assay • Dog Thrombogenicity
Summary of Substantial Equivalence	Based on the intended use, technological characteristics, and safety and performance testing, the subject Pinpoint™ GT Safety Introducer Needle met the requirements that are considered sufficient for its intended use and is as safe and as effective as predicate device cited.